THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH

UNITED STATES OF AMERICA, Plaintiff, v. PREMIUM PRODUCTION, LLC, a corporation, and RYAN PETERSON, an individual, Defendants.	**CONSENT DECREE FOR PERMANENT INJUNCTION AND ORDER GRANTING MOTION** Case No. 4:23-cv-00088-DN-PK District Judge David Nuffer Magistrate Judge Paul Kohler

The United States of America filed a Complaint for Permanent Injunction ("Complaint")[1] against Premium Production, LLC ("Premium" or "the company"), a corporation, and Ryan Petersen, an individual (collectively, "Defendants"). The parties also filed a Joint Motion for Entry of Consent Decree for Permanent Injunction ("Motion")[2] seeking the entry of a consent decree to resolve the matter. Defendants have not admitted or denied the allegations in the Complaint and consent to entry of this Consent Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the Motion is GRANTED as follows:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et seq*.

3. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by

[1] Docket no. 2, filed October 11, 2023.

[2] Docket no. 4, filed October 12, 2023.

introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (dietary supplements), as defined by 21 U.S.C. § 321(ff), that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, or held in violation of the current good manufacturing practice regulations for dietary supplements set forth in 21 C.F.R. Part 111 ("Dietary Supplement CGMP").

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by doing acts to articles of food (dietary supplements) while such articles are held for sale after shipment of one or more of their components in interstate commerce that results in the dietary supplements being adulterated within the meaning of 21 U.S.C. § 342(g)(1).

5. Upon entry of this Decree, Defendants and each and all of their owners, directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who have received actual notice of this Decree by personal service or otherwise are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly manufacturing, preparing, processing, packing, holding, and/or distributing any dietary supplement or from 880 N Pinon St, Hildale, UT 84784 (the "Establishment"), or at or from any other location(s) at which Defendants, now or in the future, directly or indirectly manufacture, prepare, process, pack, hold, and/or distribute any dietary supplement, unless and until:

A. Defendants retain, at Defendants' expense, an independent person ("DS CGMP Expert") who is without any personal or financial ties (other than a retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, or experience, is qualified to inspect the Establishment to determine whether the methods, processes, and controls are operated and administered in conformity with Dietary Supplement

CGMP. Defendants shall notify FDA in writing of the identity and qualifications of the DS CGMP Expert within ten (10) business days of retaining such expert; or, if such Expert has already been retained upon entry of this Decree, within ten (10) business days after entry of this Decree;

B. The DS CGMP Expert performs a comprehensive inspection of the Establishment and the methods, processes, and controls used to receive, manufacture, prepare, pack, repack, hold, and distribute dietary supplements and certifies in writing to FDA that: (1) the DS CGMP Expert has inspected the Establishment, methods, processes, and controls; (2) all Dietary Supplement CGMP deviations that have been brought to Defendants' attention by FDA, the DS CGMP Expert, and any other source have been corrected; and (3) the Establishment and the methods, processes, and controls used to receive, manufacture, prepare, pack, repack, hold, and distribute dietary supplements, are, in the DS CGMP Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations. The DS CGMP Expert's report of the inspection, which shall be submitted to FDA, shall include, but not be limited to, a determination that Defendants have methods, processes, and controls to ensure that they:

(1) Establish and follow written procedures setting out the responsibilities of quality control operations, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing, as required by 21 C.F.R. § 111.103;

(2) Establish product specifications for the identity, purity, strength, and composition of the finished batch of dietary supplements, and for limits on those types of contamination that may adulterate, or that may lead to the adulteration of, the finished batch of dietary supplements to ensure the quality of dietary supplements, as required by 21 C.F.R. § 111.70(e);

(3) Establish component specifications for identity, purity, strength, and composition

and for the limits on those types of contamination that may adulterate, or that may lead to the adulteration of, the finished batch of dietary supplements to ensure the quality of dietary supplements, as required by 21 C.F.R. § 111.70(b); and

(4) Prepare and follow written master manufacturing records ("MMRs") which include all required information in accordance with 21 CFR § 111.210;

C. FDA representatives may inspect the Establishment to determine whether the requirements of this Decree have been met and whether Defendants are operating in conformity with this Decree, the Act, and its implementing regulations;

D. Defendants have reimbursed FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with Paragraph 5, at the rates set forth in Paragraph 13; and

E. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in Paragraphs 5.A-D of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

6. Within thirty (30) business days after entry of this Decree, Defendants, under FDA's supervision, shall destroy all dietary supplements (including in-process dietary supplements and finished products) that are in Defendants' possession, custody, or control. Defendants shall bear the costs of destruction and the costs of FDA's supervision. Defendants shall not dispose of any finished dietary supplement products in a manner contrary to the provisions of the Act, any other federal law, or the laws or any State or Territory, as defined in the Act, in which the products are disposed. Further, if Defendants intend to transfer/sell any dietary supplement components in their possession (regardless of where they are stored), Defendants shall notify FDA in writing of their intent to transfer/sell any components at least fifteen (15) days before the transfer/sale of such components.

7. Upon resuming operations after complying with Paragraphs 5.A-D, and receiving FDA's written notification pursuant to Paragraph 5.E, Defendants shall retain an independent person (the "Auditor") who shall meet the criteria for, and may be the same person as, the DS CGMP Expert described in Paragraphs 5.A-B, to conduct audit inspections of the Establishment and the methods, processes, and controls used to receive, manufacture, prepare, pack, repack, hold, and distribute dietary supplements. Such audit inspections must entail the Auditor's physical presence at the Establishment; audit inspections may not be conducted entirely by virtual means (e.g., by camera or videolink). Thereafter:

A. After the auditor is retained, audit inspections under this paragraph shall commence no less frequently than once every six (6) months for the first year thereafter and then no less frequently than once a year thereafter for the next four (4) years. The first audit shall occur not more than six (6) months after Defendants have received FDA's written notification pursuant to Paragraph 5.E.

B. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("Audit Report") analyzing whether Defendants are in compliance with this Decree, the Act, and its implementing regulations and identifying any deviations from such requirements ("Audit Report Observations"). As a part of every Audit Report (except the first one), the Auditor shall assess the adequacy of actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service, overnight delivery service, or electronic delivery no later than ten (10) business days after the audit inspection is completed. In addition, Defendants shall maintain the Audit Reports in separate files at the Establishment and shall promptly make the Audit Reports available to FDA upon request.

C. If an Audit Report contains any Audit Report Observations, Defendants shall,

within twenty (20) business days after receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the Audit Report Observations will take longer than twenty (20) business days, Defendants shall, within fifteen (15) business days after receipt of the Audit Report, submit to FDA in writing a proposed schedule for completing corrections ("Audit Correction Schedule"). The Audit Correction Schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved Audit Correction Schedule. Within twenty (20) business days after Defendants' receipt of an Audit Report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in an FDA-approved Audit Correction Schedule, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within ten (10) business days after beginning that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

8. Upon entry of this Decree, Defendants, and all of their owners, directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons in active concert or participation with any of them, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (dietary supplements), as defined by 21 U.S.C. § 321(ff), that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, or held in violation of the current good manufacturing practice regulations for dietary supplements set forth in 21 C.F.R. Part 111;

B. Violating 21 U.S.C. § 331(k), by doing acts to articles of food (dietary supplements, as defined by 21 U.S.C. § 321(ff)) while held for sale after shipment of one or more of their components in interstate commerce that results in the dietary supplements being adulterated within the meaning of 21 U.S.C. § 342(g)(1); and

C. Failing to implement and continuously maintain the requirements of this Decree, the Act, and its implementing regulations.

9. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection; a report prepared by the DS CGMP Expert or the Auditor; or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of their noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, preparing, processing, packing, holding, and/or distributing any or all products;

B. Recall, at Defendants' expense, any product that is adulterated or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports, plans, procedures or records prepared or required pursuant to this Decree;

D. Submit additional reports or information to FDA as requested;

E. Institute or reimplement any of the requirements set forth in this Decree;

F. Issue a safety alert; and/or

G. Take any other corrective actions as FDA, in its discretion, deems necessary to bring

Defendants into compliance with this Decree, the Act, or its implementing regulations.

The provisions of this paragraph shall be separate and apart from, and in addition to, all other remedies available to FDA. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, review, travel, and subsistence expenses to implement and monitor recalls and other corrective actions, at the rates specified in Paragraph 13.

10. The following process and procedures shall apply when FDA issues an order under paragraph 9, except as provided in subparagraph D below:

A. Unless a different time frame is specified by FDA in its order, Defendants shall, within ten (10) business days after receiving such order, notify FDA in writing that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it shall explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and if they so choose, bring the matter before this Court on an expedited basis. Defendants shall continue to diligently implement FDA's order, unless the Court sets aside, stays, reverses, vacates, or modifies FDA's order. Any

review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 21 of this Decree.

D. The process and procedures set forth in paragraph 10.A.-C. shall not apply to any order issued under paragraph 9 if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief.

11. Any cessation of operations or other action described in Paragraph 9 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. Defendants may submit to FDA a written request to resume operations. Within forty-five (45) business days after FDA's receipt of a written request to resume operations, FDA will notify Defendants in writing whether Defendants appear to be in compliance with the Decree, the Act, and its implementing regulations and whether they may resume operations. In no circumstance shall FDA's silence be construed as a substitute for written notification.

12. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' operations and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and all applicable regulations. During such inspections, FDA representatives shall be permitted to have immediate access to the Establishment, including, but not limited to, all buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, and other material therein; take photographs and make video recordings; take samples of Defendants' raw ingredients, in-process materials, finished products, containers, packaging material, and other material; and examine and copy all records relating to the receipt,

manufacture, preparing, processing, packing, repacking, holding, and distribution of any and all of Defendants' products and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

13. Defendants shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, including all transportation and associated costs for FDA investigators and experts, at the standard rates prevailing at the time costs are incurred. Defendants shall make payment to FDA within twenty (20) business days after receiving an electronic invoice for payment, which shall be sent which shall be sent to rpetersen@premproduction.com with a copy to kharris@702law.com. Defendants shall make payment through the Pay.gov electronic billing system, subject to all interest, fees, and penalties applicable to delinquent payments, in accordance with 31 U.S.C. § 3717 and 45 C.F.R. § 30. As of the date that this Decree is signed by the parties, these rates are: $110.59 per hour or fraction thereof per representative for inspection and investigative work; $132.56 per hour or fraction thereof per representative for analytical or review work; $0.65 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses, where necessary. In the event that the standard rates for FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court. Defendants shall notify FDA within fifteen (15) business day if the email address at which Defendants receive electronic invoices changes.

14. Within ten (10) business days after the entry of this Decree, Defendants shall post a copy of this Decree in a common area at the Establishment, at any other location at which

Defendants conduct business, and on all websites under Defendants' control and any future website(s) under Defendants' control), and shall ensure that the Decree remains posted for as long as it remains in effect. Within fifteen (15) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph.

15. Within ten (10) business days after the entry of this Decree, Defendants shall provide a copy of the Decree by personal service, certified mail, or electronic delivery (return receipt requested) to each and all of their owners, directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons in active concert or participation with any of them (collectively, "Associated Person(s)"). Within twenty (20) business days after the date of entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

16. In the event that any Defendant becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall, within fifteen (15) business days after the commencement of such association, provide a copy of this Decree, by personal service, certified mail, or electronic delivery (return receipt requested), to such Associated Person(s), and provide to FDA an affidavit stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Person(s) who received a copy of this Decree pursuant to this paragraph.

17. Defendants shall notify FDA in writing at least fifteen (15) business days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of the company, or

the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

18. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be prominently marked "Consent Decree Correspondence – Premium – [Topic]," shall reference this civil action by case name and civil action number, and shall be addressed to the Program Division Director, Office of Human and Animal Food Operations West 4 (HAFW-4), Denver District Office, U.S. Food and Drug Administration, 6th Avenue and Kipling Street, P.O. Box 25087, Building 20-DFC, Denver, Colorado 80225-0087 or via email at orahafwest4firmresponses@fda.hhs.gov.

19. Should Defendants fail to comply with any provision of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America: Two Thousand Dollars ($2,000.00) in liquidated damages for each day such violation continues; an additional sum of Two Thousand Dollars ($2,000.00) in liquidated damages per day, per violation for each violation of this Decree, the Act, and/or its implementing regulations; and an additional sum in liquidated damages equal to twice the retail value of any distributed dietary supplements that are adulterated or otherwise in violation of this Decree, the Act, or its implementing regulations. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages

20. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), investigational and analytical expenses, expert witness fees, and court costs relating to such contempt proceedings.

21. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

22. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

Signed November 15, 2023.

BY THE COURT

David Nuffer
United States District Judge